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10/589,159	08/10/2006	Pratibha Pilgaonkar	11336.0033USWO	6952

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EXAMINER	
GREENE, IVAN A	

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1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,159	PILGAONKAR ET AL.	
	Examiner	Art Unit	
	IVAN GREENE	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,14-19,21-25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,14-19,21-25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6-9, 14-19, 21-25 and 27-31 are pending. Claims 5, 10-13, 20, 26 and 32 have been canceled by applicant. Claims 1-4, 6-9, 14-19, 21-25, and 27-31 are presented for examination on the merits.

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Claim Rejections

Claim 22 is objected to for the following informalities: the claim recites the word --pregelatinised-- which should be spelled as "pregelatinized" (clam 22 line 4). Appropriate correction is required.

Claim Rejections - 35 USC § 112 - First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. New Grounds of Rejection: Claims 2 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

2. Claim 2 recites --the dosage form in the stomach of a patient, and gradually erode within the gastrointestinal tract over a prolonged time period of ***up to 24 hours***-- [emphasis added]. The new matter is the phrase "up to 24 hours" the support pointed to in the specification (page 22, line 8) discloses "The blood levels [of Acyclovir] were monitored over 24 hours time period." The disclosed time period is clearly directed to "blood levels [of Acyclovir]" and not to the erosion of the dosage form in the patients stomach. The support provided for time period over which the dosage form will erode is as follows:

> **[0083]** The gastro-retentive controlled release compositions according to the invention includes a solubilized drug that finds utility when administered to patients in the fed or the fasting mode. The fed mode is preferred since the narrowing of the pyloric opening that occurs in the fed mode serves as a further means of promoting gastric retention by retaining a broader range of size of the dosage form. Following oral administration to a patient, the dosage form is retained in the upper gastrointestinal tract for a time period of about 30 min to about 12 hours or about 1 hour to about 9 hours or most preferably about 1 hour to about 6 hours.

which is clearly limited to "about 12 hours", not the recited "up to 24 hours". Applicant further asserts that "further support for this recitation is found in the understanding of one skilled in the art of the term 'prolonged'. " However, not no evidence for this assertion is provided.

3. Claim 21 recites --functionalized polystyrene-- for which there is no support for this limitation in the originally filed specification. And Applicant has not pointed to any

specific passage of the originally filed disclosure supporting this limitation. The Examiner was unable to find support for the limitation "functionalized polystyrene" in the originally filed disclosure.

Claim Rejections - 35 USC § 112 - Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Rejection Maintained with respect to claims 16-19; new grounds of rejection with respect to claim 30: Claims 16-19 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 16-19 recites the limitation "hydrophilic polymer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 30 recites --the...composition...according to claim 28 wherein said disintegrating agent is present...--. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. New Grounds of Rejection: Claims 1, 3, 4, 6-9, 14, 15, 18, 19, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by FALK (US 4,803,081).

Disclosure of the Prior Art

FALK discloses an extended release preparation of an active compound with very low solubility containing the active compound dissolved or dispersed in a semi-solid or liquid non-ionic solubilizer (abstract). FALK further discloses the object of their invention is to provide a preparation of a drug with very low solubility that shows prolonged and nearly constant rate of drug absorption for a long period of time and concurrently maintains a high extent of bioavailability (2:67-68; 3:1-3). FALK further discloses the object of their invention is achieved by using a solubilizer which is mixed with the drug with very low solubility (3:3-5). FALK further discloses the active compound is dissolved or dispersed in the solubilizer, and the mixture of drug and solubilizer is incorporated into a phramaceutical formulation, which gives prolonged release (3:6-7, 14-16). FALK further discloses the example drugs useful in their invention include nifedipine, felodipine, griseofulvin, digoxin, oxazepam, phenytoin and cyclosporine (3:22-24, 30-32). FALK further discloses the prefered solubilizers are polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil, comercially available under the trade names Cremophor®, Myrj®, and Polyoxyl® 40 stearate, among others (3:39-47). FALK further discloses the active compound mixed

with the solubilizer is incorporated into different kinds of known controlled release systems, such as hydrophilic gel system, beads coated with a rate controlling membrane, or tablets with an inert porous matrix (3:48-53). FALK further discloses the preferred embodiment in which the solubilized drug is combined with a hydrophilic gel system, namely a hydrophilic swelling matrix, such as HPMC (3:53-56). FALK further discloses preparations according to the invention have a ratio of active compound to solublizer ranging from 1:1 to 1:10 (4:18-21). FALK further discloses example 5 consisting of the following ingredients:

Ingredient (function)	amount (g)	percent of total
Nifedipine (active agent)	20	4.29%
Cremophor® RH 40 (solubilizer)	50	10.70%
HPMC 50 cps (swelling agent)	70	15.00%
HPMC 6 cps (swelling agent)	160	34.30%
microcrystalline cellulose (swelling enhancer)	6	1.29%
Lactose (swelling enhancer)	56	12.02%
Aluminum silicate (filler)	94	20.17%
Sodium stearyl fumarate (lubricant)	10	2.14%

FALK further discloses the composition according to example 5 was formed into hydrophilic matrix tablets containing 20 mg of nifedipine per tablet (6:32-34) From the above table the active agent is the antihypertensive, poorly water soluble drug, nifedipine; the solubilizer is Cremophor® RH 40; the ratio of solubilizer to drug is 5:2; the tablet consist of 49.3% HPMC swelling agents, and 13.3% microcrystalline cellulose/lactose swelling enhancers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. New Grounds of Rejection: Claims 2, 16, 17, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over FALK (US 4,803,081) in view of SHELL (US 5,972,389) and PATEL (US 2003/0180352).

Applicant claims

Applicant claims a controlled release oral pharmaceutical composition comprising (a) a therapeutically effective amount of one or more pharmacological agents showing low bioavailability, (b) one or more solubilizers, wherein the ratio of the solubilizer to the drug is about 20:1 to about 1:20, (c) one or more biocompatible swelling agents, and (d) a swelling enhancer. Applicant further claims the controlled release composition swells in the presence of gastric fluid such that the dosage form is retained until it erodes in the stomach of the patient. Applicant further claims the composition comprises an active agent selected from antiarrhythmic, anthypertensive, and antifungal active agents,

among others. Applicant further claims the active agent selected from nifedipine, nicardipine, cyclosporine, and digoxin, among others. Applicant further claims the composition wherein the solubilizer is selected from PEG-40 hydrogenated castor oil, among others. Applicant claims a controlled release oral pharmaceutical composition wherein the biocompatible swelling agent is the hydrophilic poylmer poly(ethylene oxide). Applicant further claims the controlled release oral pharmaceutical composition wherein the swelling enhancer is cross-linked polyvinylpyrrolidone.

Determination of the scope and content

of the prior art (MPEP 2141.01)

FALK teaches an extended release preparation of an active compound with very low solubility containing the active compound dissolved or dispersed in a semi-solid or liquid non-ionic solubilizer (abstract). FALK further teaches the object of their invention is to provide a preparation of a drug with very low solubility that shows prolonged and nearly constant rate of drug absorption for a long period of time and concurrently maintains a high extent of bioavailability (2:67-68; 3:1-3). FALK further teaches the object of their invention is achieved by using a solubilizer which is mixed with the drug with very low solubility (3:3-5). FALK further teaches the active compound is dissolved or dispersed in the solubilizer, and the mixture of drug and solubilizer is incorporated into a phramaceutical formulation, which gives prolonged release (3:6-7, 14-16). FALK further teaches the example drugs useful in their invention include nifedipine, felodipine, griseofulvin, digoxin, oxazepam, phenytoin and cyclosporine (3:22-24, 30-32). FALK

further teaches the prefered solubilizers are polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil, comercially available under the trade names Cremophor®, Myrj®, and Polyoxyl® 40 stearate, among others (3:39-47). FALK further teaches the active compound mixed with the solubilizer is incorporated into different kinds of known controlled release systems, such as hydrophilic gel system, beads coated with a rate controlling membrane, or tablets with an inert porous matrix (3:48-53). FALK further teaches the preferred embodiment in which the solubilized drug is combined with a hydrophilic gel system, namely a hydrophilic swelling matrix, such as HPMC (3:53-56). FALK further teaches preparations according to the invention have a ratio of active compound to solublizer ranging from 1:1 to 1:10 (4:18-21). FALK further teaches example 5 consisting of the following ingredients:

Ingredient (function)	amount (g)	percent of total
Nifedipine (active agent)	20	4.29%
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microcrystalline cellulose (swelling enhancer)	6	1.29%
Lactose (swelling enhancer)	56	12.02%
Aluminum silicate (filler)	94	20.17%
Sodium stearyl fumarate (lubricant)	10	2.14%

FALK further teaches the composition according to example 5 was formed into hydrophilic matrix tablets containing 20 mg of nifedipine per tablet (6:32-34) From the above table the active agent is the antihypertensive, poorly water soluble drug, nifedipine; the solubilizer is Cremophor® RH 40; the ratio of solubilizer to drug is 5:2;

the tablet consist of 49.3% HPMC swelling agents, and 13.3% microcrystalline cellulose/lactose swelling enhancers.

Ascertainment of the difference between

the prior art and the claims (MPEP 2141.02)

The difference between the rejected claims and FALK is that FALK does not expressly teach a gastric retentive dosage form, the swelling agent poly(ethylene oxide) or the swelling enhancer cross-linked polyvinylpyrrolidone.

The deficiency in the swelling agent poly(ethylene oxide) is cured by the teachings of SHELL. And the deficiency in the swelling enhancer cross-linked polyvinylpyrrolidone is cured by the teachings of PATEL.

SHELL teaches their invention relates to dosage forms that are retained in the stomach and gradually deliver sparingly soluble drugs over a time period of several hours (1:8-12). SHELL further teaches their invention provides swellable polymer systems to deliver drugs into the gastrointestinal tract (1:12-16). SHELL further teaches the preferred embodiment wherein the swellable polymer is poly(ethylene oxide) (7:57-67).

PATEL teaches solid pharmaceutical compositions for improved delivery of active agents (title). PATEL further teaches the exemplary additives that are conventionally used in pharmaceutical compositions ([0236]) including disintegrants or superdisintegrants, such as starch derivatives, cellulose derivatives, crosslinked polyvinylpyrrolidone and microcrystalline cellulose, among others ([0248]).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of SHELL with the teachings of FALK, and produce the instantly claimed invention because they each teach controlled release pharmaceutical dosage forms comprising a hydrophilic swellable matrix. It is prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a controlled release formulation comprising a hydrophilic swellable matrix (MPEP 2144.06). One of ordinary skill in the art would have been motivated to combine SHELL with FALK and produce the instantly claimed invention because the poly(ethylene oxide) hydrophilic polymer would have provided an alternative hydrophilic polymer which has already been approved for use as a pharmaceutical excipient.

It would have been *prima facie* obvious at the time the claimed invention was made to use the disintegrant cross-linked polyvinylpyrrolidone, as taught by PATEL, because the cross-linked polyvinylpyrrolidone would have been an obvious variant of the microcrystalline cellulose taught by FALK. One of ordinary skill in the art would have been motivated to use cross-linked polyvinylpyrrolidone because the well known excipient would have provided excellent swelling characteristics for the swellable matrix tablet.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Experimental Results:

Applicant's results have been considered and are not considered unexpected for the following reasons:

Applicant's results showing increased rate of swelling for those tablet containing polymers and swelling enhancers ([0085] to [0089]) are not considered unexpected results because the addition of polymers and swelling enhancers would have been expected to increase the swelling rate. The addition of swelling enhancers (disintegrants/super-disintegrants) to a polymer matrix tablet would have produced void spaces which would quickly fill with dissolution media and increase the swelling rate of the hydrophilic polymer matrix.

Applicant's results showing increased solubility of the poorly water soluble drug acyclovir would have been expected because solubilizers are known in the art to increase the solubility of poorly water soluble drugs (see PATEL [0144]).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

2. New Grounds of Rejection: Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over FALK (US 4,803,081) in view of DOSHI (US 2003/0232081).

3. In view of the 35 U.S.C. 112, second paragraph of claim 30, for purposes of examination on the merits claim 30 is being read to depend from claim 29.

Applicant claims

Applicant claims a pharmaceutical dosage form in the form of an expanding multi-layered system comprising a first layer property having at least one active pharmaceutical ingredient with an immediate release property; and a second layer having at least one active pharmaceutical ingredient with a sustained release property, one or more solubilizers, one or more biocompatible swelling agents and a swelling enhancer. Applicant further claims the pharmaceutical dosage form wherein the first layer comprises a disintegrating agent selected from starch, sodium starch glycolate, cross-linked polyvinylpyrrolidone, among others. Applicant further claims a method for preparing a pharmaceutical dosage form comprising the steps of solubilizing an active pharmaceutical ingredient and incorporating said solubilized active agent in a gastro retentive matrix having one or more swelling agents and one or more swelling enhancers.

Determination of the scope and

content of the prior art (MPEP 2141.01)

FALK teaches an extended release preparation of an active compound with very low solubility containing the active compound dissolved or dispersed in a semi-solid or liquid non-ionic solubilizer, as discussed above. FALK further teaches in example 1: felodipine was dissolved in Cremophor® RH 40 and the solution obtained was carefully mixed with the carrier materials, HPMC, xanthan gum, guar gum, and calcium phosphate (5:14-17).

Ascertainment of the difference between

the prior art and the claims (MPEP 2141.02)

The difference between the rejected claims and FALK is that FALK does not teach a multi-layered expanding gastric retentive dosage form or the swelling enhancer cross-linked polyvinylpyrrolidone.

The deficiencies in a multi-layered expanding gastric retentive dosage form and the swelling enhancer cross-linked polyvinylpyrrolidone are cured by the teachings of DOSHI.

DOSHI teaches a floating bilayer tablet which is retained in the stomach of the patient (col. 3, lines 65-67; col. 4 lines 1-4; as discussed above). DOSHI further teaches the pharmaceutical bilayer composition of their invention is effective for immediate release of active agent from one layer followed by continuous, controlled delivery of active agent present in the second layer, and the active agent in the first and second layers may be the same or different (4:28-35). DOSHI further teaches the pharmaceutical compositions of the present invention can also comprise well known ingredients such as disintegrants, povidone [cross-linked polyvinylpyrrolidone],

microcrystalline cellulose, sodium starch glycolate, and starch, among others (7:13-14, 24, 28-29, 32).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of DOSHI with the teachings of FALK, and produce the instant invention because the bilayer system of DOSHI would lead to an improved pharmaceutical product, one with instant and sustained release layers. One of ordinary skill in the art would have been motivated to combine DOSHI with FALK and produce a bilayer dosage form with instant release and continuous release properties because the immediate release layer would provide for a faster onset of drug action.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Response to Arguments:

Applicant's arguments (regarding DOSHI) filed 04/23/2009 have been fully considered but they are not persuasive.

Applicant's argument that the invention of DOSHI relies on swelling plus gas generation for imparting buoyancy to the dosage form and is therefore unlike compositions of the present invention is not convincing because the instantly rejected claims recite --an expanding multi-layered system-- and do not delineate among expanding dosage forms. Applicant is respectfully reminded that during examination it is improper to import claim limitations from the specification (MPEP § 2111.01).

Applicant's argument that DOSHI does not address in any manner, the concept of solubilizing the drug and then incorporating it in a gastro retentive matrix is not convincing because DOSHI is relied upon for the teaching of the multi-layered gastric retentive dosage form and not the incorporation of a solubilized drug. Furthermore, the use of solubilizers is well known in the art to increase the solubility of poorly water soluble drugs (see PATEL [0144]).

Conclusion

Claims 1-4, 6-9, 14-19, 21-25, and 27-31 are presented for examination on the merits. Claims 2 and 21 are rejected under 35 U.S.C. 112, first paragraph; claims 16-19 and 30 are rejected under 35 U.S.C. 112, second paragraph; claims 1, 3, 4 6-9, 14, 15, 18, 19, 21, 24 and 25 are rejected under 35 U.S.C. 102(b); claims 2, 16, 17, 22, 23 and 23 are rejected under 35 U.S.C. 103(a). No claims allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-

5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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